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09/900,576	07/06/2001	Andreas Rick	14XZ00120	4078

7590 08/21/2003  
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EXAMINER

BARBER, THERESE

ART UNIT PAPER NUMBER

2882

DATE MAILED: 08/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/900,576

Applicant(s)

RICK ET AL.

Examiner

Therese Barber

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 06 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-101 is/are pending in the application.
- 4a) Of the above claim(s) 2-9, 11, 12, 15, 16, 39 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1, 10, 13, 14, 17-38 and 41-101 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 July 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

1. The indicated allowability of claims 5-8, 10-20, 22, 24 and 41 are withdrawn in view of the newly discovered reference(s) to Horiba et al. (USPN 4,672,651). Rejections based on the newly cited reference(s) follow.
2. The applicants cancelled claims 2-9, 11, 12, 15, 16, 39, and 40 and added claims 42-93 in the Amendment dated 24 February 2003.
3. In response to the Amendment dated 6 June 2003, wherein claims 94-101 and an Information Disclosure Statement (IDS) were added to the patent application, this Office Action from the examiner will address the limitations of claims 1, 10, 13, 14, 17-38, and 41-101 and the IDS.

**NOTE:** The amendment was received on 6 June 2003, the same date that an Office Action from the USPTO was mailed to the applicants addressing claims 1, 10, 13, 14, 17-38, and 41-93.

### ***Drawings***

4. The drawings filed on 6 July 2001 are acceptable subject to correction of the informalities indicated on the attached "Notice of Draftsperson's Patent Drawing Review," PTO-948.

### ***Claim Objections***

5. Claims 1, 10, 13, 14, 17-20, 22-28, 30, 31, 35, 42, 43, 45-54, 58, 60, 61, 65, 66, 71-73, 76, 77, 83, 87 and 88 are objected to because of the following informalities:

6. Regarding claims 1, 13, 14, 35, 58, 61, 72, and 83, the limitation of “a (the) phase of heightened attenuation” is vague and indefinite in each claim. A practitioner in the art could define attenuation as the reduction in the intensity of an x-ray beam as the x-ray beam traverses matter by either absorption or deflection of photons from the x-ray beam. In addition, it well known in the art that some tissues attenuate more x-rays than other tissues, and that this difference in attenuation determine the amount of contrast in an x-ray image.

7. Regarding claim 1, the limitation of “a representative image of the contrast from the tissue of the organ is produced from the plurality of digital images” is unclear to the examiner. How does one go from having “a first image being taken before the contrast medium and at least one second image is taken after the injection of the contrast medium during a phase of heightened attenuation due to the contrast medium” resulting in representative image? The step of how the representative image is determined is missing from this claim limitation.

8. Regarding claims 10, 14, 22, 23, 24, 42, 43, 45-50, 60, 71, 82, the limitation of “at least one second images” is not grammatically correct and unclear in each claim. One could interpret that the applicants are claiming that at least two images are utilizing to form a composite second image or that the applicants are claiming that the two images are taken at intervals of one second each.

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9. Regarding claims 17-20, 51-52, and 73, the term "few" implies a range for each claim and is not clearly defined in the specification.

10. Regarding claims 26-28, 53, 54, 65, 66, 76, 77, 87 and 88, the limitation of "filter spatially" is unclear in each claim. One could interpret that the applicants are claiming that images are filtered relative to the volume or thickness of the organ that is being penetrated by the x-rays because "spatially" can be defined as relating to, occupying, or having the character of space or that the applicants are referring to "spatial filtering, which is an image enhancement processing feature, that determines the distribution of pixels of varying brightness of an image, in order, to emphasize fine details and edges of an image or to eliminate noise from an image, depending on the type of filter that is being utilized.

11. Regarding claims 30-31, the claims as amended are both dependent on claim 1 and contain the same claim limitation. However, the examiner believes that the applicants amended claim 30 to correct a typographical error and wanted to keep claim 31 as originally written.

12. Regarding claims 48-50, the limitations of "at least one second interval are taken at intervals equally distributed in time" and "at one least one second images are taken at shorter intervals of time" are unclear to the examiner. Further explanation of this limitation is needed because one could interpret that the applicants are claiming that the at least one second image is taken at a shorter intervals of time than the first image; that the images are taken at shorter intervals of time during the phase of heightened attenuation due to the contrast medium than

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after the phase of heightened attenuation; or that two images making up the second images can be taken at two different time intervals (one that is evenly distributed in time and the other that is unevenly distributed in time). In addition, these limitations are not clearly illustrated in the drawings.

***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1, 10, 21, 22, 26, 35-38, 41, 46-48, 53-54, 60, 62-66, 94, 96, and 97 are rejected under 35 U.S.C. 102(b) as being anticipated by Horiba et al. (USPN 4,672,651).

Regarding claims 1, 10, 21, 22, 26, 35-38, 41, 46-48, 53-54, 60, 62-66, 94, 96, and 97, Horiba discloses a radiological examination of an organ comprised of injecting a contrast medium into the organ to be examined (col. 5, lines 47-48); emitting an x-ray beam in the direction of the organ (col. 5, lines 48-50); taking a plurality of images after the x-ray beam has transverse the organ (col. 5, lines 30-66); wherein a first image is taken before the injection of the contrast medium (col. 5, line 30-31); wherein at least one second image is taken after the injection of the contrast medium during a phase of heightened attenuation due to the contrast medium (col. 5, lines 31-33); calculating a representative image of the contrast produced in the tissues of the organ from the images (col. 5, lines 58-65; col. 6, lines 20-27); wherein at least one second images are taken at intervals equally distributed in time (fig. 2); wherein the first image is

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subtracted from each of the at least one second images (col. 5, lines 57-61); wherein the subtracted images are filtered spatially (col. 7, line 60 to col. 9, line 37); wherein the images are converted into thickness images (col. 8, line 3 to col. 9, line 49); wherein the images are representative of the thickness of the contrast medium (col. 5, lines 58-65; col. 6, lines 20-27; col. 8, line 3 to col. 9, line 49). Horiba also discloses a CPU (11) in fig. 1 that is being utilized in the radiological examination of an organ and that the control unit (12) synchronize the contrast-medium injection start signal, the image processor unit, and the vertical sync signal (VS) from the x-ray controller (col. 5, lines 15-23 and lines 46-50).

### ***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 13, 14, 17-20, 23-25, 27-30, 32-34, 42, 45, 49-52, 55-57, 61, 67-69 and 95, are rejected under 35 U.S.C. 103(a) as being unpatentable over Horiba as applied to claims 1, 10, 35 and 41, respectively, further in view of Sharma et al. (USPN 5,596,200).

17. Regarding claims 13, 14, 17-20, 23-25, 27-30, 32-34, 42, 45, 49-52, 55-57, 61, 67-69 and 95, Horiba discloses a radiological examination of an organ comprised of injecting a contrast medium into the organ to be examined (col. 5, lines 47-48); emitting an x-ray beam in the direction of the organ (col. 5, lines 48-50); taking a plurality of images after the x-ray beam has transverse the organ (col. 5, lines 30-66); wherein a first image is taken before the injection of

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the contrast medium (col. 5, line 30-31); wherein at least one second image is taken after the injection of the contrast medium during a phase of heightened attenuation due to the contrast medium (col. 5, lines 31-33); calculating a representative image of the contrast produced in the tissues of the organ from the images (col. 5, lines 58-65; col. 6, lines 20-27); wherein the images are converted into thickness images (col. 8, line 3 to col. 9, line 49) and wherein the images are representative of the thickness of the contrast medium (col. 5, lines 58-65; col. 6, lines 20-27; col. 8, line 3 to col. 9, line 49). In addition, Horiba discloses in fig. 2, that at least 14 images are taken to form a composite second image. Horiba also discloses a CPU (11) in fig. 1 that is being utilized in the radiological examination of an organ and that the control unit (12) synchronize the contrast-medium injection start signal, the image processor unit, and the vertical sync signal (VS) from the x-ray controller (col. 5, lines 15-23 and lines 46-50).

However, Horiba fails to disclose that the images are taken from a mammography examination; that the gray level is proportional to the quantity and density of the contrast medium; and that the number of second images can range between 2 and 10.

Sharma discloses a digital x-ray imaging system that utilized semiconductor sensor elements with reduced radiation exposure to the patient, higher sensitivity, improve image resolution, image contrast, color/gray scales (table 1; col. 4, lines 3-37). In addition, Sharma discloses that after the images are taken, the information is sent to a data acquisition/storage device and then to an image processing unit, whereby a variety of image manipulations can occur including attaching gray scales, contrast enhancement and image subtraction (col. 6, lines 51-65). Sharma also discloses that x-ray imaging system can be utilized in exposing a sample such as a breast (col. 2, lines 18-27) will being cost effective (col. 7, lines 3-6).



It would have been obvious to one having ordinary skill in the art at the time the invention was made that the combination of steps as disclosed by Horiba could be utilized in image processing unit of the digital x-ray imaging system as disclosed by Sharma. According, the image processing unit can perform a number of functions that will improve the image resolution, thereby, making it easier to pinpoint the location and density of the contrast medium inside an organ, such as the breast.

18. Claims 31 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horiba as applied to claims 1 and 35 above, and further in view of Mistretta et al. (USPN 3,854,049).

Regarding claims 31 and 59, Horiba discloses a radiological examination of an organ comprised of injecting a contrast medium into the organ to be examined (col. 5, lines 47-48); emitting an x-ray beam in the direction of the organ (col. 5, lines 48-50); taking a plurality of images after the x-ray beam has transverse the organ (col. 5, lines 30-66); wherein a first image is taken before the injection of the contrast medium (col. 5, line 30-31); wherein at least one second image is taken after the injection of the contrast medium during a phase of heightened attenuation due to the contrast medium (col. 5, lines 31-33); calculating a representative image of the contrast produced in the tissues of the organ from the images (col. 5, lines 58-65; col. 6, lines 20-27; and wherein the images are converted into thickness images (col. 8, line 3 to col. 9, line 49).

However, Horiba fails to disclose that the emitting x-ray beam has a maximum intensity for a frequency in the same order as a selected absorption line of the contrast medium.

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Mistretta discloses wherein variations of the x-ray attenuation coefficient of contrast medium are a function of the x-ray energy (figs. 2-4; col. 5, line 30 to col. 7, line 9). Mistretta illustrates in figure 4, the energy of the x-ray spectra at 65 kVp and its relationship to the contrast medium. In addition, Mistretta illustrates in fig. 5, that tissue thickness is a function of the x-ray energy as it relates to the attenuation coefficient of the contrast medium (col. 7, lines 1-54).

It would have been obvious to one having ordinary skill in the art at the time the invention was made that the combination of steps as disclosed by Horiba could be modified to utilize the relationship between the x-ray attenuation coefficient of the contrast medium, the x-ray energy and variations in thickness of the organ as disclosed by Mistretta. Accordingly, the resultant methodology will have improved image resolution of the contrast medium in the images based on the knowing the relationship between x-ray attenuation coefficient of the contrast medium, the x-ray energy and thickness variation.

19. Claims 70-80, 81-93 and 98 -101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horiba and Sharma.

Horiba discloses a radiological examination of an organ comprised of injecting a contrast medium into the organ to be examined (col. 5, lines 47-48); emitting an x-ray beam in the direction of the organ (col. 5, lines 48-50); taking a plurality of images after the x-ray beam has transverse the organ (col. 5, lines 30-66); wherein a first image is taken before the injection of the contrast medium (col. 5, line 30-31); wherein at least one second image is taken after the injection of the contrast medium during a phase of heightened attenuation due to the contrast medium (col. 5, lines 31-33); calculating a representative image of the contrast produced in the

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tissues of the organ from the images (col. 5, lines 58-65; col. 6, lines 20-27); wherein the images are converted into thickness images (col. 8, line 3 to col. 9, line 49); and wherein the images are representative of the thickness of the contrast medium (col. 5, lines 58-65; col. 6, lines 20-27; col. 8, line 3 to col. 9, line 49). In addition, Horiba discloses in fig. 2, that at least 14 images are taken to form a composite second image. Horiba also discloses a CPU (11) in fig. 1 that is being utilized in the radiological examination of an organ and that the control unit (12) synchronize the contrast-medium injection start signal, the image processor unit, and the vertical sync signal (VS) from the x-ray controller (col. 5, lines 15-23 and lines 46-50).

However, Horiba fails to disclose that an article of manufacture; a program storage device readable by a machine; a computer program product for use with an image display device; that the gray level is proportional to the quantity and density of the contrast medium; and that the number of second images can range between 2 and 10.

Sharma discloses a digital x-ray imaging system that utilized semiconductor sensor elements with reduced radiation exposure to the patient, higher sensitivity, improve image resolution, image contrast, color/gray scales (table 1; col. 4, lines 3-37). In addition, Sharma discloses that after the images are taken, the information is sent to a data acquisition/storage device and then to an image processing unit, whereby a variety of image manipulations can occur including attaching gray scales, contrast enhancement and image subtraction (col. 6, lines 51-65). Sharma also discloses that x-ray imaging system can be utilized in exposing a sample such as a breast (col. 2, lines 18-27) will being cost effective (col. 7, lines 3-6). It is well known in the art the imaging processing capabilities are constantly improving with the advancement made in computer software and hardware equipment, thereby, it is inherent that computers can be

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programmed to perform temporal filtering, frame averaging, smoothing and that computers are assembled with large internal storage devices (60 or more GB hard drives); CD drives that utilize disks capable of storing 720 MB of information on one disk; and external storage devices such as ZIP drives.

It would have been obvious to one having ordinary skill in the art at the time the invention was made that the combination of steps as disclosed by Horiba could be utilized in image processing unit of the digital x-ray imaging system as disclosed by Sharma. According, the processing unit can utilize a gray scale table to map the energy from the x-ray beam and to map the contrast medium with each other, thereby, providing information on the location of the contrast medium in the organ with increased image resolution.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Therese Barber whose telephone number is (703) 306-0205. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 6:00 p.m..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward Glick can be reached on (703) 308-4858. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-4857 for regular communications and (703) 308-7722 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-4900.

tb

August 7, 2003

  
EDWARD J. GLUCK  
Supervisory Patent Examiner  
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